

Significant Legislative Rule Analysis

WAC 246-976-320

A Rule Concerning Air Ambulance Services

September 2016

SECTION 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

Currently, WAC 246-976-320 for licensure of air ambulance services requires the licensee to have and maintain accreditation by the Commission on Accreditation of Medical Transport Systems (CAMTS) or another equivalent accrediting organization. Recent federal court rulings in other states¹ have indicated a state regulation requiring all portions of CAMTS accreditation may be preempted by federal law. The federal government has authority over air ambulance rates, routes, services, and aviation safety. The courts ruled that state government has authority over air ambulance medical components only.

When the current air ambulance regulations became effective in May of 2011, CAMTS was the only nationally recognized accrediting organization for air ambulance services and most states identified CAMTS as a requirement for licensure. In 2012, the National Accreditation Alliance of Medical Transport Applications (NAAMTA) emerged as a second accrediting organization for air ambulance services. Both NAAMTA and CAMTS use a hybrid criterion for accreditation that includes review of aviation safety, configuration and clinical requirements for providing medical care. However, neither organization provides an option for a medical component only accreditation. The Department of Health (department) does not currently conduct inspections for air ambulance services because the accreditation process includes a site review conducted by the accrediting organization. Healthcare professionals who specialize in the air medical industry are contracted with by the accrediting organization to provide a comprehensive subject matter expert review of an air medical services ability to meet accreditation standards.

The department has determined that current rule WAC 246-976-320 on air ambulance services needs to be amended to address federal preemption. The proposed rule requires accreditation and includes language that provides exclusion from Federal Aviation Agency or Aviation Deregulation Act regulated activities, which addresses federal preemption and preserves the comprehensive site review process that is conducted by the accrediting organization. The proposed rule adopts minimum standards from existing accreditation requirements related to physician oversight, quality management and review of patient care data, equipment, medications, and minimum administrative requirements that provide the department with a basis for determining whether an air ambulance service meets the standards of the proposed rules. Both CAMTS and NAAMTA are approved by the department as equivalents to the standards in the proposed rule. The proposal also provides clear and enforceable standards needed to pursue complaints or disciplinary actions on a license.

The proposed rule allows an air ambulance service to obtain a department license if the air ambulance service is accredited by a department approved accrediting body that meets the minimum medical component standards in the proposed rule. An air ambulance service that is unable to obtain accreditation may apply for a waiver of the full accreditation requirement if the air ambulance service meets all components of accreditation that are consistent with the

¹ *Federal Electricity Activities Report to Congressional Requesters*. Washington, D.C. (P.O. Box 37050, Washington 20013): Office, 1997. *Gao.gov*. Web. 23 Feb. 2016. *Eagle Air Med Corp. v. Colorado Board of Health*, 570 F. Supp. 2d 1289, (D. Col.2008). *Med-Trans Corp. v. Benton*, 581 F. Supp. 2d 721 (E.D. N.C. 2008).

standards in the proposed rules other than the criteria related to the Federal Aviation Agency (FAA) or Airline Deregulation Act regulated activities.

The department is therefore proposing to amend the current rule governing the licensing and verification of air ambulance services to ensure:

- Public safety;
- Consistency in patient care provided by air ambulance services; and
- Washington state requirements do not include elements of aviation safety and configuration that are preempted by FAA regulations.

SECTION 2:

Is a Significant Analysis required for this rule? Yes, per RCW 34.05.328(5)(c)(iii) of the Administrative Procedure Act, these proposed rules require a significant analysis because it amends the qualifications or standards for the issuance of a license.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The specific statute mandating this rule is RCW 18.73.081. The statute requires the department to establish minimum standards for air ambulance services and equipment and requires the department to issue an air ambulance license.

The goal of the statute is to ensure safe emergency medical care and transport by ambulance is provided to Washington state citizens.

The specific objectives of the statute are to:

- Establish minimum medical and clinical standards for air ambulance services to provide medical care to ill and injured citizens; and
- Ensure consistent, quality, medical care can be delivered by air ambulance services in Washington state.

The rule implements the goals and specific objectives of the statute by proposing minimum standards for:

- Completion of a department approved application for licensure and verification;
- Documentation to validate aircraft registration, operations specification, and airworthiness of fixed wing and aeromedical helicopters;
- Documentation required to determine proof of insurance;
- Physician medical director oversight including quality management and a review of patient care data, and patient care protocols for medical treatment and care;
- Staffing by qualified medical personnel for all air ambulance services;
- Training and administration requirements for medical personnel for all air ambulance services;

- Aircraft configuration serving medical purposes under state purview, which is specific to providing adequate medical care; and
- Administration requirements and minimum lists of medical equipment and medications that must be available for patient care.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The genesis of the department's effort to amend the accreditation requirements in rule was due to recent federal court rulings that indicated state requirement for CAMTS accreditation are preempted by federal law.

To achieve the goal of the statute and ensure public safety and consistency in patient care is provided by air ambulance services, the department proposes to amend the current rules to:

- address the federal preemption;
- preserve the comprehensive site review process, which is conducted by the accrediting organization; and
- include provisions that provide assurance that the air ambulance service meets minimum industry standards for air ambulance medical components.

The proposed amendments also update and modernize the air ambulance services regulations to meet current industry standards to better protect the public's safety.

To achieve the specific objectives of the statute the proposed rule outlines minimum standards for the application process and required documents for licensure. The proposed rule adopts minimum standards from existing accreditation requirements related to physician oversight, quality management and review of patient care data, equipment, medications, and minimum administrative requirements. The proposed standards will provide the department with a basis for determining whether an air ambulance service meets or exceeds the standards of the proposed rule. The proposed rule also provides clear and enforceable standards needed to pursue complaints or disciplinary actions on a license.

The department evaluated the possibility that the accreditation organizations could modify their criteria to eliminate the aircraft configuration and aviation safety requirements that conflict with FAA standards. The accreditation organizations have reported they do not have current plans to change their standards.

Consequences for not adopting the rule may include legal action against the department, or having the current rule invalidated if found in conflict with federal law or court precedent. Based on these factors, there is no other alternative to rulemaking.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

Cost

The department has determined that current rule on air ambulance services needs to be amended to address the federal preemption. The proposed rule continues to require accreditation but includes language that provides exclusion from FAA or Aviation Deregulation Act regulated activities. The proposed rule addresses the federal preemption and preserves the comprehensive site review process, which is conducted by the accrediting organization.

The proposed rule would impose no new costs on existing licensed services in Washington state because it adopts minimum standards from existing accreditation requirements that all current licensed air ambulance services already meet. The proposed standards do not represent new requirements for air ambulance services. Minimum accreditation standards incorporated into the proposed rule include:

- Administrative requirements;
- Quality management program;
- Review of patient care and transport service data; and
- Medical equipment and medication lists.

A new air ambulance service seeking to operate in the state would not incur additional costs due to the proposed standards because they are standards required by accrediting organizations. A new air ambulance service would incur similar costs under the current or proposed rules except new services would have additional accreditation options to choose from. A service seeking to change its accreditation organization may realize small savings in accreditation fees.

Currently, six air ambulance services are licensed in the state of Washington, all of which hold current accreditation through CAMTS and one of which holds current accreditation with CAMTS and NAAMTA. See Table 1 for a summary of licensed air ambulance services in Washington state.

Proposed amendments update and modernize the air ambulance services regulations to meet current industry standards to better protect the public's safety.

Table 1: Licensed Air Ambulance Services in Washington State as of March 1, 2016.

Service	License Type	Base Locations
Island Air Ambulance	AIR	Friday Harbor
MedFlight One	AIR	Boeing Field, King County
Airlift Northwest	AIRV (trauma verified)	Bellingham, Arlington, Boeing Field King County, Olympia, Yakima
Lifeflight Network	AIRV (trauma verified)	Longview, The Dalles, Oregon
Reach Air Medical Services	AIRV	No bases in WA. Idaho-based service serving both Idaho and Washington

Northwest Medstar	AIRV (trauma verified	Spokane, Pullman, Moses Lake, Richland, Brewster
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CAMTS and NAAMTA have similar initial and renewal accreditation processes, which occur in phases and include the following steps:

1. Air ambulance service completes an initial application with application fee.
2. Accreditation service sends a comprehensive application to the applicant.
3. Applicant submits a completed comprehensive application within one year.
4. Accreditation service schedules and performs a site visit.
5. Accreditation service makes a determination regarding accreditation.

To become accredited by CAMTS or NAAMTA, an air ambulance service must demonstrate that they meet the standards set forth by the accreditation organization. Accreditation with both organizations lasts for three years. An air ambulance service can renew the accreditation by re-demonstrating it meets the standards in a renewal process.

An air ambulance service invests in accreditation fees, personnel and administrative resources to achieve and maintain accreditation. (See Table 2 for a summary of estimated costs associated with accreditation).

Table 2: Costs associated with accreditation occur every three years and include:

<i>Estimated Costs</i>	<i>CAMTS²</i>	<i>NAAMTA³</i>
Costs Associated with Accreditation Fees		
Application fee	\$750.00	\$750.00
Administration fee / cost for number of bases (flat fee includes 5 bases)	\$6,500.00 (\$750.00 per base over 5)	\$6,000.00 (\$500.00 per additional base)
Site audit and surveyor expenses (dependent on number of surveyors and days spent on survey)	\$3,000.00 - \$6,000.00	\$2500.00 (plus expenses reported average \$1000.00)
Costs Associated with Air Ambulance Service Planning, Preparation, and Maintenance of Accreditation⁴		

² "CAMTS." *CAMTS*. Retrieved from internet website in April 2000 and on 08 Dec. 2015

³ National Accreditation Alliance of Medical Transport Applications, *NAAMTA Medical Transport Accreditation* (NAAMTA, 2016).

⁴ As reported in Significant Legislative Rule Analysis, Proposed Amendments to Air Ambulance Services (WAC 246-976-320) and Verification of Trauma Care Services WAC (246-976-390) in 2000. Hourly wage rates were

Preparation for inspection (wage estimate for clerical 24 hours and director oversight for 8 hours in assembling application materials)	\$997.47	\$997.47
Accompanying site inspectors (wage estimate for service director for entire site survey and physician director, chief flight nurse, lead pilot for 1 hour)	\$3,178.14	\$3,178.14
Quarterly meetings required by CAMTS (wage estimate for staff required to attend meetings which are estimated at 3 hours in length with 1 hour preparation time, four meetings per year)	\$5,777.57	\$5,777.57
Total estimated costs for air ambulance services	\$20,203.18	\$19,203.18

Benefits

The proposed rule establishes minimum standards for air ambulance services to provide medical care to ill and injured citizens and promotes consistent quality of medical care delivered by air ambulance services in Washington state. The proposed standards provide a clear basis for determining whether an air ambulance service standards are equivalent to the standards in the proposed rule, and provide enforceable standards for investigating complaints on a license.

The proposed rule would impose no new costs on existing licensed services in Washington state. The proposed rule may result in a small accreditation cost savings and provide more options for accreditation entities than the current rules.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

Research efforts included a review and comparison of state requirements for licensure of air ambulance services between Washington, Arizona, Oregon, Idaho, Colorado, Utah and Montana and The National Association of State Emergency Medical Services Officers (NASEMSO) model air medical rules.

The department evaluated removing the accreditation requirement and adding an inspection requirement. However, it was determined that legislation would be required to provide authority to the department to collect a fee for inspection to fund resources needed to implement an inspection program. Currently, the accreditation site review is an integral component to ensuring public safety.

drawn from Rau, W., "1999 Medical Crew Survey," *Air Med*, Sept-Oct, 1999, 27-33 and Rau, W., "1999 Air Crew Survey," *Air Med*, Sept-Oct, 1999, 27-33. The reported wage figures were adjusted by 25 percent to account for non-wage benefits. Also, the "flight physician" wage was used as a proxy for the medical director and communications staff information was obtained through the Washington State Employment Security Department. The 2016 estimate is adjusted to reflect inflation using the Bureau of Labor Statistics CPI Inflation Calculator.

Stakeholder rulemaking meetings occurred monthly beginning in November of 2014 and concluded in June of 2016 during which time representatives from air medical services provided suggestions on possible alternatives and reached consensus on the proposed rule language.

It is likely that most, if not all, air medical services currently licensed in Washington state will maintain their current accreditation status.

The proposed rule is the least burdensome alternative to comply with because it identifies minimum standards for all air ambulance services, which they already meet. The proposal also provides a mechanism to address preemption of the FAA or Aviation Deregulation Act regulated activities.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The purpose of the current proposal is to specifically address the issue of federal preemption and update other requirements to bring the air ambulance service rule up to current industry standards. The proposed rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

These rules do not differ from any other federal regulation or statute applicable to the same activity or subject matter. The proposed rules are anticipated to eliminate inconsistencies between current state rules and federal regulations as determined by the courts.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The proposed rule has been coordinated with FAA regulations so that it only covers the medical components of air ambulance services, and does not include potential air configuration and safety requirements that are under FAA jurisdiction. There are no other laws applicable to the same activity or subject matter.